PSJ3

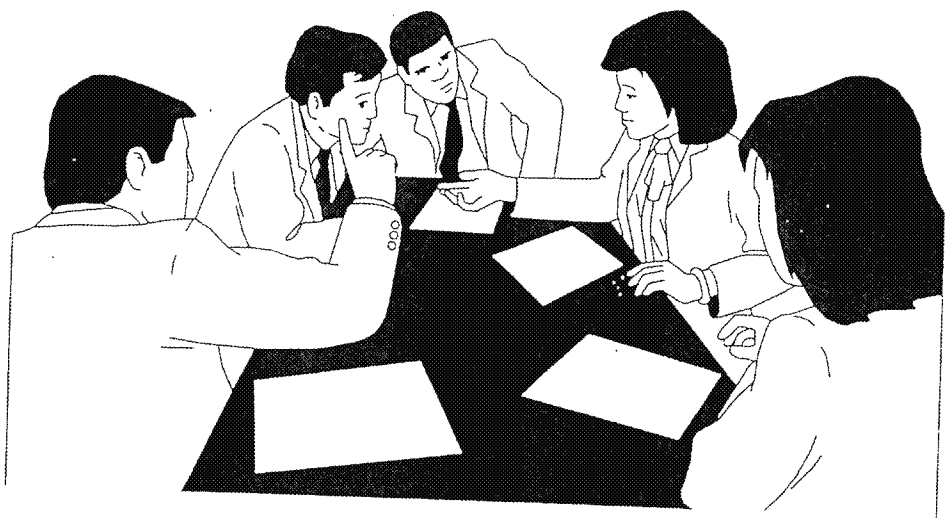
Exhibit 203A

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control
Suspicious Orders Task Force

Report to the U.S. Attorney General

by the Suspicious Orders Task Force

(Comprehensive Methamphetamine Control Act of 1996)



Washington, D.C.
October 1998

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control
Suspicious Orders Task Force

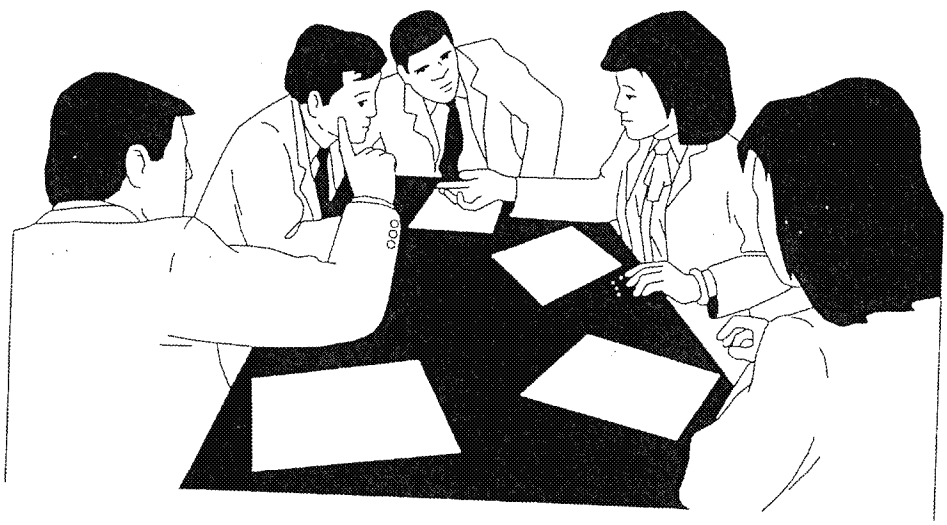
Table of Contents

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control
Suspicious Orders Task Force

Report to the U.S. Attorney General

by the Suspicious Orders Task Force

(Comprehensive Methamphetamine Control Act of 1996)



Washington, D.C.
October 1998

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control
Suspicious Orders Task Force

Table of Contents

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control
Suspicious Orders Task Force

Report to the U.S. Attorney General by the Suspicious Orders Task Force

Comprehensive Methamphetamine Control Act of 1996

I. Executive Summary

To: Attorney General Janet Reno

Subject: Report of the Suspicious Orders Task Force

The Suspicious Orders Task Force (Task Force) was formed by charter upon your signature and subsequent filing with Congress on September 3, 1997. It implemented the mandate contained in Section 504 of Public Law 104-237, known as the Comprehensive Methamphetamine Control Act (MCA) of 1996, signed into law by President Clinton on October 3, 1996.

The charter required the establishment of a task force to prepare recommendations concerning additional guidelines to be used by the chemical industry in complying with 21 U.S.C. 830 (b)(1)(A). This statute requires that certain regulated transactions which are commonly referred to as suspicious orders must be reported to the Drug Enforcement Administration (DEA) in order to prevent the diversion of listed chemicals used in the production of illicit substances.

The Task Force was comprised of 21 industry, Federal, state and local law enforcement, and regulatory officials. It met on four occasions in meetings open to the public and conducted under the rules established by the Federal Advisory Committee Act (5 U.S.C. App. 2) in Washington, D.C.; San Diego, California; St. Louis, Missouri; and San Antonio, Texas.

The Task Force took this charge seriously and the members worked diligently in acquainting each other with the roles they play, the seriousness and nature of the illicit drug production in the United States and addressing proposals and recommendations as to how governments and industry can take actions to curtail access to chemicals and other laboratory supplies while assuring legitimate needs are served.

The Task Force developed proposals for identifying indicators of suspicious orders in the various segments of industry. It considered payment practices and unusual business practices in attempting to identify prima facie suspicious orders. The Task Force found the business and payment practices in the multiple layers of the import through retail

distribution chain varied so widely that labeling specific practices prima facie indicators was not possible. The approach chosen was to recommend that the factors in Appendix A need to be considered in the totality of the transaction's circumstances.

The Task Force concluded that a single listing of meaningful, numerical parameters would be difficult. For the majority of registrants, which do not have highly automated computer ordering and tracking systems, the indicators contained in Appendix A, Exhibit I represent expanded guidance to be considered. For the segments of industry who have highly automated ordering and tracking systems, the Task Force recommends a system which starts with quantifiable parameters which track frequency of orders, deviation from prior orders, and size of orders (See Appendix A, Exhibit II). This segment of industry represents the distributors who are the suppliers to the independent and major drug chains The Task Force also developed recommendations at the retail level for recognizing suspicious transactions and suggested voluntary actions, already in use by some retail outlets, to minimize criminal access to chemicals while assuring availability for legitimate medical use (See Appendix A. Exhibit III). The Task Force discussed and considered effectiveness, costs, and feasibility for all parties in its deliberations and in its final selection of proposals, though not all questions as to cost were identifiable by this group. A follow-on report will be prepared to provide cost estimates, identifiable to DEA, state and local governments, and industry in order to implement the recommendations. This report will also provide the results of a look at additional quantifiable parameters that industry can use to identify suspicious orders. This report will be submitted to the Attorney General by November 1, 1998.

The Task Force requests your review and approval of the recommendations contained in Section V of this report. These recommendations fall in the following general areas:

1) Improve the guidelines as to the definition of "suspicious" in regards to listed chemicals. This involves publishing a more detailed list, or criteria, for defining "suspicious", and more detailed guidance in how to use the criteria.

2) Improve communication between industry, law enforcement and regulators. This involves improvements to DEA's Internet Web Site; a new periodical to be published by the DEA; and increased attention to suspicious orders at DEA sponsored conferences & working groups.

3) Improve information/data transfer. This involves employing technology that will streamline the process of identifying and reporting, to and within DEA, what appears to be a suspicious order. In short, computerizing the process.

II. Background

In the early nineteen nineties, the United States began to experience a public health crisis due to the illegal production and abuse of methamphetamine. This plight created a groundswell of calls for additional government efforts to deal with the tremendous epidemic of illicit methamphetamine production and abuse. Further, this public health crisis has been fueled by a rapidly changing supply picture involving methamphetamine produced in both Mexico and the United States. Governments at all levels have reacted with new strategies and legislative initiatives. One critical element in those efforts has been a focus on restricting access to the chemical compounds necessary to produce methamphetamine and its chemically similar drug homologs, amphetamine and methcathinone.

The processes most frequently used in the illicit production of methamphetamine in the United States changed from an early reliance on the Phenyl-2-Propanone (P2P) synthesis, which was the technique used largely by outlaw motorcycle gangs, to those syntheses which used the chemicals ephedrine, pseudoephedrine, and phenylpropanolamine The use of these readily available chemicals caused the production picture to rapidly change. Large criminal organizations based in Mexico and California emerged and b a producing illicit methamphetamine both within Mexico and the western United States. Th ready availability of these chemicals also gave rise to a tremendous number of smaller clandestine laboratories run by domestic criminals in a pattern of production and abuse tha is still spreading eastward.

The laboratory activities controlled by the Mexican organizations focused on ephedrine acquired in bulk form. These materials were obtained from the international market until the end of 1995 by which time those supplies were largely curtailed through international cooperation in verifying the legitimacy of shipments. Within the United States, the controls initiated when Congress passed the Chemical Diversion and Traffickin Act (CDTA) in 1988, removed bulk ephedrine powder from the illicit supply being diverted from the commercial market. Drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine play a dual role in this drama. These chemicals serve as precursors for the production of methamphetamine, amphetamine, and methcathinone, as well as appearing in over-the-counter (OTC) products approved by the FDA for treatment of coughs and colds. These products were exempted from control by the CDTA because of their legitimate role and because their diversion was not then perceived as a significant problem. But, because these products are largely sold "over-the counter", and therefore readily available, they rapidly became the target of choice to supp the raw materials to the illicit market. Because of this exemption, domestic criminal

elements focused their attention on obtaining ephedrine tablets. A variety of "rogue" companies emerged that specialized in providing these tablets in large volumes.

With the passage of the Domestic Chemical Diversion and Control Act (DCDCA) in late 1993, the exemption for single entity ephedrine tablets was removed (effective in April 1994). Traffickers began a switch to the remaining exempted OTC products beginning in the fall of 1994. During 1995, and continuing to the present, the focus has been on obtaining those phenylpropanolamine, pseudoephedrine, and ephedrine combination products.

With the signing into law of the Comprehensive Methamphetamine Control Act (MCA) of 1996, the exemptions for ephedrine combination products were removed immediately and pseudoephedrine and phenylpropanolamine products were removed effective October 3, 1997. The passage of the MCA has begun to have positive effects in curtailing the supply available to criminal elements. Further, the MCA brought an existing control regime to a new set of legitimate handlers of controlled chemicals; those in the OTC supply chain. These newly regulated entities included chemical suppliers and pharmaceutical supply chains whose OTC product distribution had not previously been required to comply with Controlled Substances Act (CSA) List I controls.

Industry expressed concerns regarding statutory requirements to report to DEA what are commonly referred to as suspicious orders. Industry made requests to the Congress for additional guidelines and procedures to specifically define what constitutes a suspicious order and a request to explore development of an electronic means to transmit such reports. These concerns were included in Section 504 of the MCA establishing this Suspicious Orders Task Force.

III. Formation

The Suspicious Orders Task Force was formed as a result of a mandate included in the Comprehensive Methamphetamine Control Act of 1996 (MCA), chemical control legislation amending the Controlled Substances Act of 1970 (CSA). Further, Section 504 of the MCA imposed on the Task Force the restrictions outlined in the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2).

While the findings of the Task Force may have more wide ranging applications, because of the nature of the enabling legislation, the Task Force limited its area of consideration to domestic issues regarding suspicious orders of List I and List II chemicals The Task Force was structured to provide the Attorney General with a preliminary report containing the Task Force Operational Plan by October 3, 1997 and a report within two years after the date of enactment of the MCA (October 3, 1998).

The DEA's Office of Diversion Control (OD) was responsible for providing the necessary administrative and clerical support to the Task Force. Such support included, but was not limited to:

1. Arrangements for public meeting space
2. Photocopying
3. Note taking during meetings
4. Transcribing and final preparation of minutes and proposals
5. Preparation and dissemination of the required Federal Register notices
6. Preparation of required administrative reports (under FACA)

The administrative expenses of the Task Force were paid out of existing Departme of Justice funds from DEA appropriations. Recurring expenses included, but were not limited to, the following:

1. Publicly accessible meeting space for all four full Task Force meetings.
2. Administrative preparation and maintenance of reports, records, statements, and working papers generated by the Task Force's activities.
3. Per diem and travel expenses for public sector members of the Task Force and administrative staff.
4. Human resource requirements which included three administrative staff; two par time assignments and one full time assignment.

Note: **Private sector participant costs were borne by the participants and their respective employers.**

All expenditures including per diem, travel expenses, other expenses, fees, and compensations were made in accordance with the limitations outlined in the FACA. Further, all members of the Task Force served at the discretion and pleasure of their respective employers.

The four Task Force meetings were held in geographically diverse areas to encourage interested public comment from the broadest number of those concerned with suspicious chemical orders. Meeting locations, based on the illicit methamphetamine production conditions existing at the time of the passage of the MCA, were: the west coast (San Diego, California); in the Midwest (St. Louis, Missouri); and on the east coast (Washington, D.C.). These meetings were held for the express purpose of gathering information by collecting data and hearing testimony from experts in law enforcement and industry. The fourth meeting was held in San Antonio, Texas, for the express purpose of drafting recommendations and composing this report.

The Chairman of the Task Force was the Chief of the Chemical Operations Section of DEA's Office of Diversion Control. In accordance with the FACA, the Chairman selected a Designated Federal Official (DFO) to oversee the operations of the Task Force from the administrative staff at DEA Headquarters. The DFO was a non-voting member of the Task Force.

The Task Force consisted of 21 voting members selected from law enforcement, regulatory agencies, and the chemical and pharmaceutical industries. Within the confines of the MCA and logistical and budgetary limitations, the Task Force consisted of:

1) **Two members of the DEA investigative work force.** These members were selected because of their knowledge of chemical and/or clandestine laboratory investigations.

2) **One member from the United States Attorney's Office for the Southern District of California.** This member was selected because of her expertise in prosecuting cases involving List I and II chemicals and clandestine laboratories.

3) **Five members from State and local law enforcement.** These members were selected from the nationally recognized International Association of Chiefs of Police (IACP), the National Association of Diversion Drug Investigators (NADDI), the California Bureau of Narcotics Enforcement (CA/BNE), the Missouri State Highway Patrol, and the Missouri Attorney General's Office.

4) **Two members from regulatory agencies.** These members were selected from The National Association of Boards of Pharmacy (NABP) and the National Association of State Controlled Substances Authorities (NASCSA).

5) **Four members from the chemical industry.** These members were selected from the Chemical Manufacturers Association (CMA) and the National Association of Chemical Distributors (NACD).

6) **Five members from the pharmaceutical industry.** These members were selected from the wholesale and retail pharmaceutical marketing associations. The National Non-Prescription Drug Manufacturers' Association (NDMA), The National Community Pharmacists' Association (NCPA), The National Wholesale Druggists' Association (NWDA), The Food Marketing Institute (FMI), The National Association of Chain Drug Stores (NACDS) each provided members.

7) **Additional Membership.** At its inception, the Chairman retained the option of adding up to two additional members to the Task Force. The proposed composition and representation of the Task Force were made public through the Federal Register. While no one came forward in response to the announcement, testimony received during the meetings indicated the need for additional representation. After consultation with the other Task Force members and at the request of the American Wholesale Manufacturers' Association (AWMA), the Chairman added one additional member to the Task Force to represent the service merchandise industry. (See Appendix E, Membership List)

Method of Operation

1) The Task Force operated in a round table fashion consisting of "a committee of the whole." This format did not require the formation of sub-committees and, due to the limited scope and resources of the Task Force, none was formed until the drafting of the finished report had begun.

2) The report contains a majority opinion and such minority opinion(s) as are deemed appropriate by the Task Force Chairman and the DFO. The majority opinion was determined by consensus of the majority of members.

3) The Task Force Chairman, in conjunction with the DFO, prepared, and circulated in advance, a meeting agenda, with time table, including relevant topics submitted by other Task Force members, any administrative matters slated for discussion an

clearly defining a limited time period to receive verbal statements from interested members of the public.

4) In accordance with the FACA, all meetings of the Task Force were open to the public with appropriate notices appearing in the Federal Register. Interested parties were permitted to attend the Task Force meetings, appear before the Task Force and present verbal and written statements. Any written statements submitted to the Task Force were disseminated to all Task Force members and made available to the attending public. Additionally, the public was offered the opportunity to sign up for distribution of those handouts that were not available at the meeting. All submissions were made a part of the meeting record. All verbal comments were recorded by court reporters and were made a part of the official record.

5) The first meeting included a statement as to the operation of the Task Force, its procedures, and agenda. Further, the first meeting included an ethics briefing. The second and third meetings included testimony by invited speakers and experts in clandestine laboratory investigations. Both of these meetings also included extensive testimony from the attending public. Discussions of presented materials included the attending public as well as the Task Force members. During the fourth meeting, the foundation for this report was drafted. Again, the attending public was allowed to observe and participate in the discussions.

IV. Task Force Activities

The Suspicious Orders Task Force met on four occasions. The first meeting was held on December 16 and 17, 1997 in Arlington, Virginia. The second was held in San Diego, California on February 4 and 5, 1998. The third in St. Louis, Missouri on April 7 and 8, 1998. The fourth and final in San Antonio, Texas on May 19 and 20, 1998. The mandate that governed the formation of the Task Force (See Appendix C) is contained in Section 504 of the MCA. The responsibilities included:

- Developing proposals to define suspicious orders of listed chemicals,
- Developing quantifiable parameters which can be used by registrants in determining if an order is a suspicious order which must be reported to DEA, and
- Developing provisions as to what types of payment practices or unusual business practices shall constitute prima facie suspicious orders.

Further, the Task Force was tasked with evaluating the proposals with consideration for:

- Effectiveness,
- Cost and feasibility for industry and government, and
- Other relevant factors

Lastly, the Task Force was charged to address electronic reporting of suspicious orders to DEA.

The first issue considered by the Task Force was defining suspicious orders. The wide diversity of business activities represented by importers, manufacturers, wholesale distributors, and retail distributors was recognized early in the first meeting. A great portion of this first, and subsequent meetings, was devoted to member descriptions of the normal business activities and what they recognized as cause for suspicion in customer orders. At the first meeting a chart of business activity levels was drawn up to aid discussions. It was apparent that many segments had little knowledge and/or contact with other segments within the supply chain that handles regulated chemicals. The Task Force rapidly concluded that recognizing suspicious orders meant recognizing different circumstances at the differing levels of industry. No single definition of suspicious order nor prima facie payment or business practice was going to be attainable.

To address the issue of developing multiple layered suspicious order guidance a list of indicators keyed to various industry segments was prepared and reviewed by the Task Force. This list was developed to replace an earlier one, contained in the DEA *Chemical Handlers Manual*. The new list provides current, more specific indicators, as particularly requested by the newly covered wholesale portions of industry. The list was considered and referenced by all three drafting working groups at the San Antonio, Texas meeting and is presented in Appendix A, Exhibit I.

Industry suggested that this list be caveated to specifically articulate that these are merely indicators, no one of which may be a prima facie indicator that independently requires reporting to DEA, but needs to be viewed in the totality of the proposed order or transaction. The language of the caveat appears in recommendation A1. This recommendation commits all areas of industry to consider these indicators and DEA to be flexible in reviewing industry assessments of possible suspicious orders.

The industry segment which includes the highly automated wholesale drug distributors were specifically interested in quantifiable parameters with which they could use their computer power to assist in identifying possible suspicious orders in their Over-The-Counter (OTC) product lines. This segment of industry receives their orders virtually 100 percent electronically. These orders come from established customers or owned outlets, where the OTC product orders are a small portion of the items handled, representing small numbers of the total volume sent to any customer. They proposed using a modification of a system now in use for controlled substance suspicious order reporting. This system is contained in recommendation B1 and Appendix A, Exhibit II. This modified segment of the industry is not exempted from considering indicators contained in Exhibit I and requested a specific caveat, similar to the one above, which is contained in recommendation B2. Possible law enforcement requests for adjustment are addressed in recommendation B4.

The issues of suspicious orders in another OTC wholesale segment were highlighted by law enforcement testimony. Large orders, ranging from several to hundreds of cases per shipment, destined for outlets that do not also handle controlled substances, such as convenience stores, sundry outlets, and food marts have figured prominently in recent investigations. These volumes suggest that these customers are not operating at the retail level belying their outward appearance. This is the most prevalent area for diversion to illicit use. Two industry associations which represent businesses in this area of industry, testified that normal legitimate business practice would produce shipments in amounts similar to the highly automated wholesale drug distributors. Individual store orders should be enough to fill shelf stock only, because they are frequently serviced and have virtually

no "back room" storage space. Typically, OTC products would be only one among many items delivered by the wholesale company. This area of industry frequently does not have the same level of computer support as that referenced above. The suspicious order indicators in Appendix A, Exhibit I shall be used by this segment for guidance, while standard reporting requirements apply. Recognition that an alternate reporting system may be within the capabilities of some companies in this area is contained in recommendation B5.

The Task Force recognized that if any level of industry failed to exercise vigilance in identifying suspicious orders, the system would fail to deter diversion. The issue of companies functioning as brokers, potentially allowing both the distributor and the broker to evade responsibility, was pointed out. Law enforcement members cited a number of examples where this concern has already arisen. There is no broker category for domestic activities authorized by the Controlled Substances Act (CSA) and its implementing regulations. The Task Force working group at the wholesale level presented the proposal to require all persons or entities which operate at the wholesale level be governed by the same regulatory requirements that cover distributors at wholesale. See recommendation B6.

A significant issue arose which called into question the coverage of suspicious orders reporting at the retail level. The MCA defines most individual retail OTC distributions under the 24 gram threshold or in specified packaging as not being regulated transactions. The reporting requirement applies only to regulated transactions. This presents a rather large problem, as illustrated at the St. Louis meeting, which highlighted the prevalence of small methamphetamine laboratories in the Midwest. These laboratories are easily supplied with the necessary precursors with merely a few quick trips to retail outlets, buying only the maximum allowed by the 24 gram threshold at each location. This type of laboratory activity is also frequently encountered in other areas of the country. This includes California which is widely known for very large laboratories. The Task Force concluded it would be remiss if it didn't make recommendations in this highly vulnerable area.

The Task Force elected to recommend emulation of the many excellent voluntary initiatives undertaken by industry. These programs were described to the Task Force during testimony where the role for voluntary actions, that exceed mandated minimums, was highlighted by the importers, manufacturers, and wholesalers of bulk chemicals. The bulk chemical handlers reported that they have had programs to prevent diversion in place

for many years and had participated in crafting the existing guidelines in DEA's *Chemical Handlers Manual*. Industry representatives described their programs as based on the "know your customer" principle of responsible business practice. Task Force members at the importer / manufacturer level provided a model control program (See Appendix B) and a description of their Responsible Care® program. One of the national drug store chains presented their retail sale limit program. The recommendations for voluntary programs contained in this report drew, in large measure, from these and other member's recommendations whose national associations are actively promoting such efforts to supplement regulatory requirements.

The first recommendation deals with publication by DEA of a list of suspicious order / transaction indicators. This document is specific to the retail setting and should be used in conjunction with the indicators in Appendix A, Exhibit I. This recommendation is found at C1 and the list is found in Appendix A, Exhibit III. (Additional explanatory text accompanies recommendation C1.) The Task Force recognized a concern that voluntary actions at the retail level to reduce access and discourage potential purchases for illicit use could have a potential implementation cost to the stores. These actions would have to be weighed against the abuse problem in the area. Some pharmacy outlets took these measures when the losses to "shelf sweepers" and shoplifters became severe. These measures are contained in recommendations C3 and C5. Cooperation between industry and law enforcement to develop local initiatives in areas of methamphetamine or other related drug issues is outlined in recommendation C4.

Issues dealing with the ease with which even mildly determined persons can currently obtain sufficient OTC products for illicit methamphetamine production generated a proposal to move pseudoephedrine OTC products into schedule V of the CSA. The majority of the Task Force felt that such a move could not be supported at the Federal level in light of enactment of the MCA. Most Task Force members felt that placing pseudoephedrine and other List I chemicals under more restrictive control was an action more appropriately taken by individual states. This is the only issue that drew formal dissenting comments. These are included in Section VI, Dissenting Opinion / Recommendation.

Presentation of U.S. import data for ephedrine and pseudoephedrine covering the years 1990 through 1996 generated considerable discussion. Especially notable is a sharp upturn in pseudoephedrine imports following the 1994 effective date of controls on single entity ephedrine products. The industry association representing manufacturers of national brands and large generic lines indicated their members saw no similar rise in production

and distribution during this period. This led to industry sponsored proposals regarding a medical needs assessment, an import reconciliation proposal, and the description of a reluctant but possible path to future quota action. These are found at recommendations D3, A2, and A4 respectively.

Another broad issue the Task Force identified was the continuing requirement for current information. Industry and law enforcement need to be informed in order to make progress in dealing with changing diversion patterns. The need for education within industry and the continual exchange of information between law enforcement and industry was addressed by the Task Force in a series of recommendations. While aware of the requirements for "public-private education" initiatives contained in Section 503 of the MCA, the Task Force recommendations were proposed to insure that the issue of suspicious orders remained in the forefront.

The recommendation contained in B7 articulates distributor responsibilities for monitoring trends in the ordering practices of their customers. Occurrences to be noted include any changes that might signal shifts in diversionary practices. These changes might indicate a switch to alternate chemicals or processes by the illicit laboratory operators. Further, it proposes to make DEA responsible for education and training al parties as well as establishing a communications process to advise industry of these trend The recommendation at C2 proposes that DEA publish a list of "Hot Zones" to advise industry and the public of where illicit methamphetamine production is a problem.

Continuing to address the issue of communication, the recommendation in D5 proposes that DEA consolidate the Chemical and Drug Industry conferences and cover a series of related topics of mutual interest. It also calls for a new DEA periodical publication focused on materials used in the clandestine production of illicit drugs.

The need to use modern communication techniques is addressed in recommendati at A3 and D6 which call for the upgrading of DEA's web-site to provide ready access tc variety of information of use to industry. One especially unique proposal appears in bot recommendations. This proposal deals with publishing, on paper and electronically, a li: of "prohibited persons" modeled after a similar list published by the Department of Commerce, Bureau of Export Administration. Such a listing would help satisfy at least portion of industries desire to have prima facie indication of suspicious transactions. Th proposal assumes that due process and privacy considerations will be handled in proceedings prior to publication. The types of information to be published would incluc the identities of convicted illegal drug manufacturers; convicted chemical diverters; businesses prohibited from distributing chemicals because of revoked registrations;

businesses denied registration "for cause" or businesses under court ordered injunction. This information would be of direct benefit to distributors who are approached by these entities.

The mandate issue of electronic reporting was considered by the Task Force. It was concluded that designing such a system was beyond the expertise of the Task Force members. The discussion included a suggestion to build a system utilizing Internet access. Recommendations for a DEA follow-on process to build such a system were made at B3 and D4.

While the Task Force considered the cost of implementing these recommendations, it concluded that an accurate cost assessment was not feasible with the current membership. However, concerned that state authorities must participate in the suspicious orders process for it to work effectively and that funding at that level might not be sufficient to the task, the Task Force composed the recommendation in D2. It proposes that DEA form a working group(s) to identify state resources needed to implement the recommendations of the Task Force and identify available funding sources. Finally, recommendation D1 would task DEA with providing the Attorney General the detailed description and costs associated with resources required to implement any adopted recommendations. This will be addressed in the final report to be submitted by November 1, 1998.

A major change in the understanding of the roles that both industry and law enforcement play in the overall methamphetamine problem evolved throughout the four meetings. Industry acknowledged a new understanding of how their segments are subject to diversion and expressed a willingness to go beyond current efforts to curtail it. Law enforcement recognized the need to have regular dialogue with industry and each other and a new awareness of industries ongoing efforts. Industry segments handling non-regulated chemicals and laboratory supplies described by law enforcement witnesses were outside the current mandate. These items will be included in the Special Surveillance List mandated by the MCA and will require DEA to initiate future meetings with industry that also involve State and Local law enforcement and regulatory officials.

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control
Suspicious Orders Task Force

NOTE: Reference Materials that were presented at the various meetings as well as the Transcripts of the meetings are available by contacting:

Suspicious Orders Task Force
Designated Federal Official
C/O Drug Enforcement Administration
Office of Diversion Control
Washington, D.C. 20537

V. Recommendations

Because of the complexity of this issue, the Task Force concluded that the term "suspicious order" had different meanings at different levels of the manufacturing and distribution chain. Accordingly, the recommendations of the Task Force and the definition of "suspicious" are presented in a tiered fashion giving meaning to "suspicious" that is relevant to the different groups: Importers & Manufacturers; Wholesale Distributors; and Retail Distributors. While retailers were arguably not strictly included in the mandate that established the Task Force, the members felt that retail was an important part of the entire manufacturing and distribution chain and that they would be remiss in not making recommendations to help curtail suspicious transactions at that level. Additionally, the wholesale distributor to retail and retail distributor levels most commonly come into contact with individuals who would divert products used in the production of controlled substances. The Task Force additionally believed that it was necessary to develop some recommendations that would bolster the ability of DEA to provide continuing information to industry. Those recommendations are contained in Other Issues, Section D.

The recommendations that follow are divided into the different logical segments of the listed chemical distribution progression. The composition and wording of the recommendations were prepared by Task Force members most familiar with the areas of concern with input and review from the entire Task Force. Also included as Appendix B is a voluntary industry model program for reviewing List I chemical orders provided by one industry representative on the Task Force. A follow-on report will be prepared to provide cost estimates, identifiable to DEA, state and local governments, and industry in order to implement the recommendations. In addition, this report will provide the results of a look at additional quantifiable parameters that industry can use to identify suspicious orders. This report will be submitted to the Attorney General by November 1, 1998.

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control
Suspicious Orders Task Force

A. Importers & Manufacturers

The Suspicious Orders Task Force recommends:

A1 That the introduction to the DEA publication of "Suspicious Orders Guidelines" in the Chemical Handlers Manual be rewritten to include as follows:

"The following guidelines are intended to assist chemical manufacturers, distributors, wholesalers and retailers to be alert to suspicious orders involving listed chemicals. Consistent application of these guidelines will help industry assist DEA in preventing the diversion of legitimate chemical products to illegal drug manufacturing and use. The guidelines are intended to apply to all aspects of commercial chemical manufacturing and distribution. It is important that the guidelines are applied to the totality of any particular circumstances. No individual indicator listed below is independently a suggestion that a given order is suspicious and/or reportable to DEA. Questions concerning potentially suspicious orders should be directed to the local DEA office."

A2 That DEA, in consultation with industry, design an effective means to req the accurate accounting of imports and exports of list one chemicals through routine and reliable industry reporting of differences and discrepancies between declared intentions to import and actual imports of listed chemicals.

This recommendation reflects industry's intent and ability to assist DEA in reconciling actual imports with declared imports; to alert DEA to commercial circumstances susceptible to diversion; and responds to the Task Force's request f allowing DEA's accurate accounting of listed chemical imports, particularly ephedrine and pseudoephedrine. Current law does not require Importers or Exporters to notify DEA of undelivered, reduced, or canceled orders after making an initial declaration via DEA form 486 to Import or Export listed chemicals. Thi situation can effect DEA's assessments of potential diversion by producing erroneo statistics. Industry will continue to supply DEA information specific to individual shipments with differences and discrepancies.

A3 That the Attorney General support additional DEA resources for information sharing and industry outreach, especially through improvements to the DEA web-site.

In addition to the general goal of seeking better access to information from DEA, industry has frequently requested specific identification of persons whose activities are prima facie indicators which industry should regard as suspicious. One industry member informed the Task Force that currently, the Department of Commerce, Bureau of Export Administration, maintains a prohibited persons list on their Internet Home Page. These persons are forbidden from doing export business for a declared period of time. This may well serve as a model for informing legitimate business of persons and firms who have previously been convicted of illegal drug production activities or who are barred from engaging in regulated chemical transactions.

A4 That the Attorney General not consider import quotas on ephedrine, pseudoephedrine and phenylpropanolamine without first producing specific and demonstrable evidence that import quotas will reduce diversion of these chemicals or products which contain these chemicals into clandestine laboratories for purposes of manufacturing illicit drugs. Such evidence shall, at a minimum, include an estimate of the legitimate domestic demand for products which contain List I chemicals, as well as analysis of the potential impacts on the availability of legitimate products which contain List I chemicals.

Any consideration of possible import quotas should include a cost-benefit analysis assessing the impact to date of the MCA and the possible short and long term impacts of import quotas on commodity chemicals trade, consumer product prices, prevention and diversion programs and illegal drug manufacturing. While the Task Force suggests consideration of possible import quotas on certain chemicals, the Task Force acknowledges its lack of expertise on the possible effects and effectiveness of import quotas on illegal drug manufacturing and trade. The Task Force encourages completion of appropriate assessments and analyses in order to determine whether import quotas will merely provoke consumer and chemical price increases without combating diversion or demand.

B. Wholesale Distributors

The Suspicious Orders Task Force recommends:

B1 That those in the wholesale drug distribution supply chain who are able use the DEA-approved Suspicious Order Monitoring System in use by wholesale drug distributors for controlled substances as enhanced by the Task Force in Appendix A, Exhibit II, for the reporting of potentially suspicious orders of listed chemicals includin ephedrine, pseudoephedrine and phenylpropanolamine. DEA will be responsible, upon subsequent industry request, for providing the gram weight equivalent and base code ingredient data necessary to support the baseline suspicious order monitoring system fc listed chemicals analogous to that currently in use to monitor controlled substance orders. For registrants in this supply chain who do not choose to use this data, Customer and Customer category average purchases or other DEA-approved methods will be used to identify orders which could be considered excessive or suspicious.

This is basically what is done for Schedules II through V controlled substance: for which base code ingredient and/or gram weight equivalent information is no available from DEA. This will be considered the baseline " reporting system." The specific parameters of the Baseline System are included as ***Appendix A, Exhibit II.***

As a result of the Task Force work, an enhanced Suspicious Order Monitoring Reporting System (of 1998) was recommended by the DEA. Industry, using the historical data from their current (baseline) Suspicious Order Monitoring system, modeled the improved "targeting" of customers whose orders might be considered suspicious or excessive. The enhanced system significantly reduced the number of potentially suspicious or excessive purchase reports, thereby providing the DEA and other law enforcement agencies with a much sharper focus to detect those who may engaging in illicit activity.

This enhanced suspicious order reporting system (the Suspicious Order Reporting System of 1998) will create reports when a customer's purchases exceed t acceptable parameters in the "baseline" system two (2) consecutive months or in thr (3) of any moving six (6) month period.

B2 That those in the wholesale drug distribution supply chain who are able to support the automated, Suspicious Order Reporting System of 1998 requirements included in Appendix A, Exhibit I, shall not be deemed non-compliant solely on the basis that they fail to take into account one or more of the "indicators" included in Exhibit I.

The Task Force looked at the provision in the regulation which directs registrants to report "extraordinary quantities" or "unusual or excessive loses" and other suspicious circumstances involving listed chemical transactions (21 CFR 1310.05). Industry leaders at this level commented that DEA has provided some guidance for industry on complying with the listed chemical suspicious order reporting requirement in the past, but much of this guidance is not applicable to many in the wholesale drug distribution supply chain segments. Incorporated here by reference and included as ***Exhibit I*** *of the Task Force recommendations are enhanced DEA Chemical Handlers Manual indicators for the identification of orders which may be considered excessive or suspicious. It was recognized that these indicators may be more applicable to the operations of other chemical handlers, because many of these indicators are not usual and customary business practices of the legitimate wholesale drug distribution industry.*

As an example, the typical national wholesale drug distributor:

(1) Receives virtually one hundred percent (100%) of their orders via electronic commerce (with no human interaction),

(2) Receives orders totaling 60,000 - 70,000 order lines nightly from 400 to 1,200 customers,

(3) Makes delivery within 12 - 18 hours of order receipt, and

(4) Distribution of regulated OTC chemical products in these order lines is usually a small portion and a small volume in any single customer order.

The typical customer base is: independent and chain retail drug stores and hospital/ institutional accounts. As a result of this level of activity and complexity, additional technology-based processes are necessary.

B3 That funding for and development of computer infrastructure sufficient to receive, process, analyze and redistribute time-sensitive enforcement information from suspicious order reporting to DEA field offices and other regulatory agencies and law enforcement groups for legal action be addressed within DEA's appropriations.

B4 That, in exceptional cases, some individualizing of reports may be necessary to best address problems with listed chemical diversion in a particular area. To the extent agreed, changes to local/regional reporting are made at the request of the DEA and/or a state or local regulatory agency, the member of industry will seek, and DEA and/or the agency will provide, a letter stating the revised Suspicious Order Monitoring System meets the requirements of the DEA and/or the agency.

B5 That in recognition of the fact that many wholesale distributors do not also distribute controlled substances, they may, with written permission of their field DEA office, Special Agent in Charge (SAC), maintain an alternative DEA approved reporting system. In no case are they exempt from the record retention, readily retrievable requirements. These companies shall use the indicators in Exhibit I as appropriate to their businesses as additional guidance in fulfilling their responsibilities to identify and report suspicious transactions.

B6 That any person or entity that engages in any regulated transaction of List I chemicals with another entity (retailer/broker/dealer/distributor or a term with substantially the same meaning) engaged in the sale or distribution of a List I chemical to the general public shall be required to provide the same reports to DEA as the industry segment most generally described as wholesale distributor.

B7 That wholesale distributors of chemicals and lab supplies, in addition to the indicators in the Chemical Handlers Manual, shall be cognizant of trends or changes in ordering patterns of their customers. These trend or/and changes may be indicative of a suspicious transaction as regulations and law enforcement efforts cause those involved in the manufacturing of illicit substances to adapt and replace existing processes requiring alternative chemicals or processes. DEA will proactively establish an education, training and communication process to advise industry on essential chemicals and equipment, questionable combinations of chemicals and identifiable or emerging patterns of diversion as they relate to illicit drug manufacturing activities.

C. Retail Distributors

The Suspicious Orders Task Force recommends:

C1 That DEA publish a list of indicators which aid retail entities to identify "suspicious transactions." (Our recommended list of indicators is presented in Exhibit III.) Because there is confusion as to whether sales in the retail OTC setting can fall within the statutory requirements of 21 U.S.C. 830 (b) (1), commonly referred to as "suspicious orders" which require specific reporting to DEA, statutory language should be clarified if it was Congress' intent to have transactions under threshold amounts or other retail sales fall within that definition.

This Task Force was formed to provide updated definition of "suspicious orders" so that industry would know when such sales were occurring and meet their statutory obligation to report such orders. However, one industry witness contended that in the retail over-the-counter (OTC) context this process is unnecessary because the Comprehensive Methamphetamine Control Act of 1997 (P.L. 104-237) currently provides for precise and clear guidance concerning suspicious transactions in a retail store, meaning sub-threshold transactions are the only parameter that need be taken into account.

As specified in the statute approved by Congress, two important thresholds govern retail sales of listed chemicals to customers. Under the first threshold, retail stores that sell "ordinary over-the-counter pseudoephedrine or phenylpropanolamine product" are completely exempt from various DEA requirements including registration, record keeping and reporting. The term "Safe Harbor" is widely used by industry to describe the MCA definition of "ordinary over-the-counter". This exemption is applicable to those products that are packaged in blister packs of not more than two dosage units per blister and with no more than a total of three grams of base ingredients in the package. Additionally, the "safe harbor" provisions impose no limitations on the number of products that a customer may purchase in a single transaction.

The second threshold established by Congress covers OTC drug products containing pseudoephedrine or phenylpropanolamine that are not in "safe harbor" packaging and all combination ephedrine products. As specified by law, retail sales of combination ephedrine products and OTC drug products containing pseudoephedrine or phenylpropanolamine that are below the threshold of 24 grams in a single transaction are exempt. In contrast, the sale of these affected OTC drug products that are not in safe harbor packaging and combination ephedrine products

that are in excess of the 24 gram threshold in a single transaction, triggers a series of regulatory requirements for a retail store including registration, record keeping and reporting obligations.

While the law requires the reporting of some (suspicious) customer transactions, retail stores still need to be vigilant and exercise sound judgment in monitoring suspicious transactions or activities. The Task Force feels that it would be instructive to promulgate a list of factors which are indicators of suspicious transactions and the list is contained in Exhibit III. Industry members of the Task Force have noted that they are concerned about creating a list of factors which would mandate reporting to DEA on their part. The list presented in Exhibit II should be distributed or made known within the industry to enable retailers and their employees to recognize suspicious transactions and prevent possible diversion

It is important to note that a number of retail stores have already initiated voluntary policies which limit the number of products that can be purchased in a single transaction, and that retail stores understand that unusually large consumer purchases or theft of OTC products containing listed chemicals should be rep d to DEA.

C2 That DEA publish a list of methamphetamine "hot zones" to make industry an the public aware of regions where methamphetamine is a problem.

Methamphetamine manufacture and the accompanying diversion of ingredie chemicals by manufacturers or their criminal partners are a significant problem in many areas of the United States, though, it is not yet a problem in every region. order to make the DEA's and state and local law enforcement's knowledge of a regional methamphetamine problems known, it was suggested that DEA produce a list of methamphetamine "hot zones" which could serve to notify the retail industr in certain geographic areas where methamphetamine is a problem, that it may be necessary and appropriate to adopt measures to prevent diversion of ingredients f methamphetamine manufacture. The list could be regularly updated as identified criminal trends change. The list should be publicly available on the Internet, Federal Register, etc., to individual retail entities and retail associations alike so that legitimate industry can respond to this problem.

C3 That, in regions or locations where methamphetamine is a problem, it is recommended that retailers consider actions which would control placement within the store of products containing regulated chemicals or materials used in the manufacture of methamphetamine. Such actions could include the following:

1) placing such items in highly visible locations within a store;
2) posting signs advising customers that identification may be requested if such items are purchased;
3) development of a store program where identification is requested of customers attempting to buy unusual quantities or suspicious combinations of such products;
4) limiting the amount of stock on the sales floor; and
5) placing such products in a restricted area of the store.

The Task Force considered proposals relating to limitation of accessibility of chemicals on the sales floor. Industry representatives on the Task Force noted that placing OTC cough and cold preparations in restricted areas (e.g., in a restricted area of the store, behind the counter or in showcases or cages on the sales floor) would unduly inhibit consumers who have legitimate need for the products. In addition, they noted that due to the quantity and variety of such products on the market, most stores are not designed with enough physical space to place such products behind the counter. Finally, they noted that such a measure would place an enormous financial burden on the retail entity. However, the Task Force recognized the implications of this recommendation. These actions are intended to be voluntary and reflect industry endeavors already in place in some high problem areas. This commentary is intended to give voice and consideration to industry articulated concerns.

The Task Force also discussed suggestions relating to requesting identification at the point of sale, as that action often inhibits those intending to purchase items for diversion from doing so. It was noted that it would be difficult to identify criteria to evaluate whether such a sale should go forward. Factors such as name, age, or address would not be good measures. However, where there is a local problem and it appears that notifying customers that identification may be requested for OTC purchases of chemicals and products containing chemicals, posting signs advising customers of that fact may be effective in preventing diversion.

C4 That where there is a regional or local methamphetamine or other related drug problem, retail industry work closely with local law enforcement representatives to address local needs and problems. Responsive, voluntary initiatives are recommended to present a rapid and effective measure to counter diversion.

C5 That the following voluntary initiatives for retail stores that sell OTC products which contain List I chemicals be adopted:

1. Establish a policy whereby a retail store will only stock and sell OTC drug products that come in safe harbor packaging. Restrict (e.g., place in a restricted area of the store) or prohibit the sale of bulk 50-count or larger size packages.

2. Implement a policy at store level to limit the number of OTC products that a consumer may purchase in a single transaction. A number of retail chains have already instituted such policies on a voluntary basis, and business considering a voluntary program should look to other successful and effective programs instituted in their region or employed by similar type business.

3. Where feasible, implement a point-of-sale control system at cash registers. Separately or in conjunction with the "sale quantity limitations" program implemented above, stores may consider an electronic or "point of sale" check-out system that would display an operator message or void the transaction.

4. Post signs in retail stores to advise consumers and employees that the store reserves the right to limit the number of OTC products that may be purchased in a single transaction.

5. Review and, where appropriate, initiate programs that will enhance security at store level to minimize theft. Such programs could include source tagging of OTC drug products and the use of electronic surveillance cameras.

6. Limit sales of red phosphorous and iodine crystals. Monitor large sales of lye and iodine in retail stores. Educate sales force about illegitimate use of these products, as well as suspicious combination purchases.

7. Implement merchandising programs that would limit the number of OTC product packages that are on display on retail store shelves to discourage "shelf sweeping."

8. Initiate a program to monitor orders and shipments of OTC drug products from a company's distribution center to all company stores.

9. Promote educational programs for management and the work force, such as "Common Sense Compliance with the Methamphetamine Control Act of 1996", to help the retail community understand how they can work to ensure that legitimate OTC drug products are not diverted to clandestine labs for the illicit production of methamphetamine. Educate sales force regarding the illegitimate uses of List I chemicals, as well as the importance of identifying possible suspicious "combination purchases" of products.

10. Become involved with demand reduction efforts regarding the dangers of methamphetamine use, and work together to develop appropriate strategies to fight this serious drug abuse program.

As has been discussed throughout the Task Force meetings, voluntary initiatives have been commenced in many segments of the retail industry. The Task Force feels that such voluntary initiatives should be encouraged and employed where appropriate. This listing of suggested initiatives is to be disseminated by DEA and state and local agencies. Communication techniques to be employed include publications, training programs, Internet Home Pages, and industry meetings. A number of industry associations have committed to disseminating this information to their members via their routine communications.

D. Other Issues

The Suspicious Orders Task Force recommends:

D1 That DEA provide to the Attorney General the detailed description and costs associated with resources required to implement the recommendations of the Task Force.

D2 That DEA working groups identify state resource needs to implement the recommendations of the Task Force and identify funding sources.

D3 That the Attorney General convene a panel of medical and industry experts for the purpose of determining the legitimate medical need for products containing List I chemicals for the United States population.

D4 That a follow-on working group (Federal, state, industry) be established for the purpose of: defining resources/cost/design specifications and system hardware support necessary to transmit/receive/assimilate/distribute suspicious order moni n and other relevant information necessary to facilitate effective law enforcement efforts.

D5 That DEA consolidate the Chemical and Drug Industry conferences currently hosted at 18 month intervals as well as increase and make routine communication between law enforcement representatives and representatives of both the chemical and pharmaceutical industries to ensure ongoing:

Information exchange
Education regarding:

- Trends
- Industry practices
- Prosecution successes
- DEA's publication of a periodical focusing on chemical and drug products and lab supplies used for the clandestine production of illicit drugs.

D6 That the DEA Internet Web Site be upgraded to include:

-DEA responsibilities
-Guidance Documents
-DEA Forms
-Hot Areas - Trouble Spots, Current Issues, Chemical Changes, etc.
-Federal Register Notices
-Advanced Rule Making, if appropriate
-Registrant Verification
-FOIA
-List of List I Chemical Products including UPC and NDC identifiers
-Manufacturers' Voluntary Efforts
-A system, based on the principles currently in use by Food and Drug Administration (FDA) and Bureau of Export Control Administration (BXA), to provide notice of persons and firms who have been convicted of illegal drug production or prohibited from engaging in handling controlled chemicals. These listings would be made only after appropriate action has been taken which provides for due process. *(see recommendation A3.)*

VI. Dissenting Opinion / Recommendation

The following letter was forwarded to Chairman Wolf by Task Force member Richard Markuson:

Dear Bill:

Sorry I will not be able to attend the Suspicious Orders Task Force meeting in San Antonio. As I indicated to you earlier, I will be attending the NABP national meeting.

Your letter indicates that work will begin on drafting the proposal to the Attorney General. Assuming this is the last meeting of the Task Force, I do have some concerns or our recommendations. There has been a lot of dialogue of what is meant by suspicious and what our specific task is to be. If we polled the members of the committee, I'm sure we would all agree, that we have a major problem with the illicit manufacturing of methamphetamine and amphetamine. We all know the problem precursors are ephedrine, pseudoephedrine and phenylpropanolamine [phenylpropanolamine]. The ephedrine has been controlled to a great extent, in a number of states, including Idaho, by placing i prescription. The major problem now is pseudoephedrine, phenylpropanolamine and its widespread availability. I believe anybody purchasing these products for other than its intended medical use, and in particular in large quantities, becomes a suspicious order. I am also concerned that quantities of these products are packaged in bulk quantities of 100 or larger for retail sales. If we really want to get serious about this problem, then we hav to address the retail sales of these products. I am not convinced that programs put in plac at the retail level have been effective in deterring the sales of these products to individual who wish to manufacture illicit drugs. How do we accomplish this and still have the products available to the public for their intended medical use? This to me is the questio that needs to be answered, and should be addressed by this committee. There has been some discussion by the committee concerning retail sales but seems to stop short if the suggestion is made that sales should be restricted in some manner e.g. placing these products in Schedule V for OTC sales, even though this has occurred with ephedrine. Language could be included that would allow someone other than the pharmacist to make the sale. Combination products that meet certain criteria could be exempt from any recor keeping requirements. We don't seem to have a problem requiring positive ID for tobacc and alcohol products. There is no reason the same thing can't occur when purchasing these products and still be available to the general public. This has become a national public health problem, let alone the cost of clean up for these labs has

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control
Suspicious Orders Task Force

become astronomical, costing states millions of dollars. The bottom line should not be influencing what needs to be done to stop the production of these illicit drugs. We need to lay aside our self interests in this issue and get to the heart of the problem. It's time to do what needs to be done.

I appreciate the opportunity of working with the committee and look forward to some positive and worthwhile outcomes.

Please include this letter as my recommendations to the Attorney General.

Sincerely,

Richard K. Markuson, R.Ph.

Department of Public Safety
MISSOURI STATE HIGHWAY PATROL
Colonel Weldon L. Wilhoit, Superintendent

1510 East Elm Street
Post Office Box 568
Jefferson City, MO 65102-0568
Phone: (573) 751-3313 (V/TDD) • FAX: (573) 751-9419

An Internationally Accredited Agency

Mel Carnahan
Governor

Gary B. Kempker
Director

September 21, 1998

Mr. William J. Wolf Jr.
Suspicious Orders Task Force
Drug Enforcement Administration
Washington, DC 20537

Dear Mr. Wolf:

I have reviewed a draft of the final report to the Attorney General concerning the recommendations and findings of the Suspicious Orders Task Force. I agree that the definition of "suspicious order" has different meanings at different levels. I support the Task Force's recommendations concerning importers and manufactures and wholesale distributors; although, I do not believe the task force fulfilled its obligation by clearly defining reporting methodologies that are simple and quantifiable.

I must admit that I am very disappointed in the Task Forces's reluctance to provide a clear definition of a "suspicious order" at the retail level. During the time this Task Force has met I have witnessed the methamphetamine explosion move into the states of Oklahoma, Kansas, Iowa, Illinois and Arkansas. The meth production problem in Missouri has increased rapidly since the inception of this task force and has increased monthly since the Comprehensive Methamphetamine Control Act (MCA) of 1996 was signed on October 3, 1996. In simple terms, the Comprehensive Methamphetamine Control Act (MCA) has not adequately addressed the over-the-counter (OTC) sales of products containing pseudoephedrine or phenylpropanolamine. The language in the Suspicious Orders Task Force report fails to provide statutory recommendations concerning OTC products but rather ducks the issue by stating the OTC products have already been addressed by the MCA which provides for precise and clear guidance concerning suspicious transactions in a retail store. It is very obvious that this "precise and clear" guidance is not working.

It is true that many retailers have initiated some form of voluntary policy concerning sales limits on these products. I am sure these actions have been instrumental in reducing large scale diversion in some selected areas but most voluntary sales limits are still six times higher than the normal amount of product purchased by a legitimate consumer. This action requires the meth producer to

expend more time and energy in procuring their precursors by making several trips to the store or by traveling to numerous locations and making the maximum purchase allowed at each until they accumulate the required amount of precursor to satisfy their needs. These retailers should be commended for taking a proactive approach but more stringent regulations are needed.

Missouri currently ranks as the number two state in meth lab seizures. Each month since 1995 this state has witnessed an increase in meth lab seizures. It is anticipated that somewhere between 700 and 1000 meth labs will be seized in Missouri in 1998. Although no firm statistic can be quoted, it appears that 95% of the pseudoephedrine/PPA diverted to meth lab production in Missouri is diverted at the retail level. I suspect these figures are also fairly accurate for the states surrounding Missouri. I would encourage the Attorney General to consider placing these products in Schedule V for OTC sales as has been done with ephedrine. Positive ID could be required as in now mandatory for tobacco and alcohol products.

In closing, some type of stringent retail regulation must be adopted to curtail this epidemic. Please accept this letter as a dissenting opinion as it pertains to the task force recommendation concerning retail level distribution. I would like to thank DEA for allowing me to be a part of this Task Force.

Sincerely,

James F. Keathley

JAMES F. KEATHLEY, Captain
Division of Drug and Crime Control

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control
Suspicious Orders Task Force

Appendix A

EXHIBIT I

Suspicious Orders Identification Criteria

Each regulated entity is most familiar with its customers and circumstances surrounding the orders it processes. The chemical industry must use its best judgment in identifying suspicious orders. The following are provided in order to assist the industry in identifying suspicious orders.

ALL LEVELS/ALL CHEMICALS
(May not apply to all retail settings*)

- New customer or unfamiliar representative or established customer who begins ordering listed chemicals.*
- Customers who don't seem to know industry practice or who fail to provide reasons for an order at variance with accepted legitimate industry practice.
- Customer whose communications are not prepared or conducted in a professional business manner.*
- Customer who provides evasive responses to any questions or is unable to supply information as to whether chemicals are for domestic use or for export.
- Customer who has difficulty pronouncing chemical names.
- New customers who don't seem to know Federal or state government regulations.*
- Customer whose stated use of listed chemicals is incompatible with destination country's commercial activities or consignee's line of business.*
- Customers who want predominantly or only regulated chemicals.
- Customers who want multiple regulated or surveillance list products, particularly if in contrast to customary use and practice.
- Customer who is vague or resists providing information about firm's address, telephone number, and reason for seeking that chemical.*
- Customer who provides false or suspicious addresses, telephone numbers or references.
- Customer who is vague or will not furnish references for credit purposes.*
- Customer who refuses or is reluctant to establish a credit account or provide purchase order information.*
- Customer who prefers to pay by cashiers check, postal money order, etc.

EXHIBIT I (continued)

- Customer who desires to pay cash.*
- Customer who wants to pick up the chemicals outside of normal practice in the suppliers experience.
- Customer with little or no business background available.*
- An established customer who deviates from previous orders or ordering methods.
- Customers who want airfreight or express delivery.
- Customers who want chemicals shipped to PO Box or an address other than usual business address. (e.g. residence address)
- Customer using a freight forwarder as ultimate consignee.
- Customer who requests unusual methods of delivery or routes of shipment.
- Customer who provides unusual shipping, labeling, or packaging instructions.
- Customer who requests the use of intermediate consignees whose location or business is incompatible with the purported end users nature of business or location.
- Above threshold hydrochloride Gas or Iodine sales to a non-commercial customer.

DISTRIBUTOR (Non-retail) REGULATED OTC PRODUCTS

- Customers who don't want to tell you what area they will resell into.
- Customers who don't want to tell you in what volumes they will resell.
- Customers who refuse to tell you who their customers are.
- Customers who don't have limits on resales.
- Customers who push to buy more than your sales limit.
- Customers who repeatedly buy your sales limit at the shortest interval you set.
- Customers who don't know what his customers limits are on individual resales.
- Customers who resell to non-traditional outlets for regulated OTC products. e.g. hair salons, head shops, drug paraphernalia stores, liquor stores, record stores, video shops.
- Customers who resell large volumes into the "independent convenience store" market.
- Any customer who asks for large bottle sizes, 60 count or higher.
- Customers who buy only the largest size available.
- Customers that don't sell other pharmaceutical products or appear to sell those other products in token amounts.
- Any customer that resells multiple cases that flow through to individual retail outlets.

EXHIBIT I (continued)

- New customers who want to sell regulated OTC products into California, Arizona, Nevada, Oregon, Utah, Washington, New Mexico, Texas, Kansas, Missouri, Arkansas,
- Any customer who wants to sell to an outlet relocated from California, Missouri or Kansas to any of the states identified in the prior sentence.
- Any customer who wants to export, particularly to Mexico, Canada, or Southeast Asia.
- Customers who will not provide you with evidence of registration with DEA. (Or having applied by the following deadlines: Nov 13, 1995 for single entity ephedrine; July 12, 1997 for ephedrine combinations products; Dec 3, 1997 for pseudoephedrine and phenylpropanolamine products.)
- Customers who will not provide you with evidence of applicable state registrations/licenses.
- Customers who sell mail order and who don't report sales to DEA monthly. (Note they must also be registered.)
- Nominal retail customers who sell above the Federal, "Retail," 24 GM individual sale limits.

WHOLESALE DRUG DISTRIBUTION INDICATORS

- Individual pharmacies that intend to export.
- Individual pharmacies or chains that won't set a voluntary limit for individual sales at some fraction of the Federal limit to qualify as a retail outlet.
- Pharmacies that stock large shelf volumes in stores that have repeated thefts or other sales problems.

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control
Suspicious Orders Task Force

EXHIBIT II

SUSPICIOUS ORDER REPORTING SYSTEM OF 1998
For Use in automated tracking systems

The Current Calculation Being Used
for List I Chemicals and Schedule II - V Controlled Substances

Terms & Definitions

This formula is used to calculate the quantity which, if exceeded in one month, constitutes an order which may be considered excessive or suspicious.

1) Add purchase quantities for the last 12 months for all customers within same Distribution Center and for customer type (Hospital, Pharmacy or Other) for any List I chemical containing item stocked by the Distribution Center.

2) Add Customer months for every record used in above total. (Months within the last 12 that customer purchases of the item were not zero).

3) Divide total quantity purchased by the total customer months.

4) Then multiply by the factor below to give the maximum amount that the customer can order per month before showing up on the suspicious order report.

   Note: Factor equals 3 for C-II and C-III Controlled Substances Containing List I Chemicals and 8 for C-III **N**-V Controlled Substances and non-Controlled OTC products containing List I chemical items.

5) At the end of each month, a report will be transmitted to DEA (separate reports for List I Chemicals and Schedule II - V Controlled Substances) of all purchases of List I Chemicals and/or C-II-V Controlled Substances and List I containing OTC items by any customer whose purchase quantities exceed the parameters (above) any (2) consecutive months or in three (3) of any moving six (6) month period.

Using a computer to manage and report on high volume transaction business activities with extremely short order cycles times (receipt to delivery) is the only viable, cost effective methodology for the reporting of orders which may be considered excessive or suspicious.

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control
Suspicious Orders Task Force

EXHIBIT III

Factors which May Suggest a Suspicious Transaction

Retail Level - Regulated Products and/or Combination Purchases

-- OTC customers who ask for more than the transaction limit in effect.
-- Customers who are part of a group, each of whom buys the transaction limit.
-- Customers who buy the transaction limit on the same day and/or repeatedly within a few days.
-- Customers who buy only the largest size available at the transaction limit.
-- Customers who buy other methamphetamine processing products at the same time as the regulated products (alcohol, Coleman fuel, acetone, road flares, drain cleaners, iodine, muriatic acid, rock salt, starting fluid (ether), dry gas (alcohol), coffee filters, large amounts of matches, etc.).
-- Customers who indicate they will resell or export.
-- Iodine customers who don't have a legitimate reason for the purchase or who don't have an articulable reason for the volume requested.
-- Customers who purchase three or more of the following products in combination: alcohol, Coleman fuel, acetone, road flares, drain cleaners, iodine, muriatic acid, rock salt, starting fluid (ether), dry gas (alcohol), coffee filters, large amounts of matches, etc.
-- Customers who purchase Iodine crystals or pellets with any other item from the surveillance list.
-- Customers who purchase hydrogen peroxide and over four fluid ounces of tincture of iodine.
-- Customers who want to purchase red phosphorous or iodine and any other item from the surveillance list.
-- Customers who want to pay cash when other forms of payment would be customary.

There may be a legitimate explanation for a purchase that presents one or more of these factors. The list is presented as a guide to instruct retailers and their employees as to which transactions may be suspicious.

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control
Suspicious Orders Task Force

Appendix B

The following is an industry suggested model program for evaluating chemical orders to determine if they are reportable as suspicious orders:

CONTROL AND MINIMIZATION OF SUSPICIOUS ORDERS FOR BULK CHEMICAL IMPORTERS, MANUFACTURERS AND DISTRIBUTORS

Overview

Proper identification of suspicious orders for bulk chemical importers, manufacturers and distributors should involve the establishment of an "approved customer list" for customers who are eligible to receive List I chemicals, and the development of attendant procedures relating to, *inter alia*, list maintenance, and suspicious orders. In particular, a system should be developed to monitor the approved list, and, for each order, review a list of order characteristics which would categorize the order as suspicious.

System Characteristics & Review

A multi-part control effort is necessary to minimize sales of List I chemicals to anyone but "legitimate" pharmaceutical manufacturers, and other select customers. The cornerstone of this effort should consist of the customer approval process. If a completely new customer attempts to order any List I chemical, a brief information package should be developed for an independent approval of the customer. Included in the approval should be the designation of approved ship-to locations. If an existing, approved customer wishes to add a new ship-to location, an independent approval of this new location should be made pursuant to the attached process.

Factors and Considerations for Approval

The following should be considered "red flags" in the approval process, and should place the company on notice of the potential for diversion by a customer.

- ✔A customer who is vague about its firm's address, telephone number, and reason for desiring a listed chemical.
- ✔A customer who will not furnish references or who is vague about furnishing references for credit purposes.
- ✔A customer who desires listed chemicals for reasons at variance with accepted legitimate industry practice.
- ✔A customer who is not a member of a trade, professional, or business association.

- ✔A customer who furnishes false or suspicious addresses, telephone numbers, or references.
- ✔A customer who refuses or is reluctant to establish a credit account or provide purchase order information.
- ✔A customer with little or no business background information available.
- ✔A customer whose communication either by telephone, mail, or other means is not conducted or prepared in a professional business manner.
- ✔A customer who purchases unusual quantities or combinations of chemicals or glassware in contrast with customary practice and usage.
- ✔A customer whose stated use of listed chemicals is incompatible with destination country's commercial activities or consignee's line of business.
- ✔The use of intermediate consignee(s) whose location or business is incompatible with the purported end user's nature of business or location.

Detailed Approval Considerations

All persons and entities requesting receipt of any quantity of a List I chemical should first be approved to receive such material. Any new ship-to address should be considered a new customer for purposes of these guidelines.

Classes of Customers

Potential recipients of List I chemicals should be placed into four categories:

- ➤Approved customers. These are customers authorized to receive List I chemicals on an ongoing basis.

- ➤Manufacturing requesters. This category includes any person or entity requesting to receive List I Chemicals for the purpose of manufacturing a product using the material. In general, such requesters can be further categorized into known manufacturers and non-known manufacturers. The screening process for these sub-categories should differ to some degree, and is discussed below.

- ➤Research requesters. This category includes any research and/or evaluation concern, including University researchers, commercial labs, R&D operations within manufacturing companies, and other such organizations.

- ➤Other requesters. Entities requesting to acquire List I chemicals which are not included in any of the preceding three categories, such as law enforcement agencies, educational organizations, freight forwarders, redistributors, etc.

Recommended Procedure

The following information should be gathered prior to the investigation process:

1) Requester Name
2) Requester Address
3) Requester Corporate Affiliation(s)
4) Officer(s) of any concerned Corporate Entity
5) Material Delivery Address
6) Copy of Requester's DEA License or copy of Application
7) Requester's statement of end-use signed by an Officer of the Corporation
8) List of product(s) to be produced using requested material
9) Sample(s) of said product label(s)
10) Requester's business references (at least three)
11) Requester's banking references
12) Statement of how the customer was acquired
13) Statement of business unit's knowledge of the requester's business
14) Type and amount of material requested
15) Any unusual terms requested, i.e., immediate shipment, delivery to a freight forwarder, etc.

The company's credit department, or appropriate function, should provide the following information:

1) Credit decision and line extended
2) Credit report (Dunn & Bradstreet) produced within the preceding 90 days
3) Statement of any previous credit experience with this customer or related corporate entity
4) Primary Screening

Primary screening consists of the following:

➤Is the requester a known company in the business of making a product containing the requested material? If so, call a developed point of contact (POC) and verify the information contained in the application.

- Is the requester an existing customer for List I chemicals, and now requesting a different ship-to destination? If so, call the customer POC and confirm the legitimacy of the order.

- Is the requester a known research entity, such as a major University? If so, call the Research facility parent corporation's Director of Security to confirm the legitimacy of the order. In the case of a University, call to the Office of the Chairman of the appropriate department, usually Chemistry.

- Is the requester a subsidiary of an existing List I chemical customer, or of a known manufacturer? If so, call the customer POC and confirm the legitimacy of the order.

- Is all information contained in the request file within normal parameters? The following norms apply:

  Requester Name - should be readily available from other sources and should match the Dunn & Bradstreet report.

  Requester Address - should match the Dunn & Bradstreet report.

  Requester Corporate Affiliation(s) - should match the Dunn & Bradstreet report.

  Officer(s) of any concerned Corporate Entity - should match the Dunn & Bradstreet report, and should be verified through the appropriate State Department of State.

  Material Delivery Address - should appear on the Dunn & Bradstreet as the principal or an additional site for the company, and the address should be appropriate to the statement of use. For example, if the request is for a manufacturing quantity, the delivery address should not be a lab.

  Copy of Requester's DEA License - must be valid for the material requested, for the disposition requested. The requested ship-to address should match the license address. In general, very few entities have a license to export List I chemicals, and so disposition requests for delivery to shipping points and freight forwarders are suspect.

  Requester's statement of end-use - must be unambiguous. "To manufacture a pharmacological preparation" or such language is unacceptable. The specific product, or the major company for whom toll manufacturing is being done, should be cited. In cases where the requester claims to be tolling, the relationship should be verified by contacting the major manufacturer in question.

  List of product(s) to be produced - will be a recognizable product, something the supplier company should be familiar with.

Sample(s) of product label(s) - will be recognizable and state the presence of the requested material in the ingredients portion of the label. The label should agree with the name of the entity requesting the material or the entity which the requester asserts is the principal customer (in tolling operations).

Requester's Business references (should request three references) - Should be consistent with the requester's size and business.

Requester's Banking References - Should give the name of a particular bank officer and be consistent with the Dunn & Bradstreet report.

Statement of how the customer was acquired - If the customer was solicited by supplier's sales force, the sales person should provide specific information about the requester.

Statement of supplier's knowledge of the requester's business – supplier's POC should advise as to the nature of the customer's business and stature in the industry, if known. If the requester is not known in the industry, the supplier should so state.

Type and amount of material requested - Should be consistent with the size of the requester's business, the stated end-use, and the product label.

There should be no unusual terms requested, i.e., immediate shipment, delivery to a freight forwarder, etc.

If, after a primary screening, there are still unresolved issues with the request, the supplier will begin a detailed evaluation.

Detailed Evaluation

Detailed evaluation consists of the acquisition of independent verification of as much of the request file information as possible and necessary. In performing a detailed evaluation, the following steps will be taken, in sequence, until such time as the Security Manager has reason to believe that the order is legitimate or has reason to believe that the order is inappropriate. The steps are:

Contact any other corporation security department which may have specific information on, or knowledge of, the requester.

Contact the DEA office (compliance) in the geographical region of the ship-to address. Discuss the request with the compliance officers at that office for their input.

Contact references provided in the application. Verify information provided, especially that all principles of the business entity have been disclosed.

Determine if the ship-to address site has ever been visited by a supplier salesperson. If so, interview that individual.

The application should be rejected at any point in the evaluation process if there are indications of inconsistencies in the information provided, invalid licenses, or other disqualifying information. Rejected applications should be so endorsed. Apparent attempts to divert should be reported to appropriate authorities.

Factors and Considerations for Individual Transaction Review

Sales representatives or order processing personnel must be trained to look for suspicious transactions *even with* approved customers. Specific transactional "red flags" are as follows:

The order is substantially greater than orders previously received from the customer.

The order is received more frequently than previous orders.

The size or frequency of such order is inconsistent with the known nature of the customer's business.

The customer is offering an unusual method of payment.

The customer is offering to pay a price substantially in excess of the normal market.

The customer is requesting delivery to an unknown site, or to a site different than that normally shipped to, or to a location that is not a known manufacturing site for finished pharmaceuticals.

The customer is indifferent to grade or particle size.

The customer desires to pay cash and wants to pick up the chemical(s).

An established customer deviates from previous orders or ordering methods.

An unfamiliar representative of an established customer orders listed chemicals.

The customer who has difficulty in pronouncing chemical names.

The customer wants a listed chemical shipped to a post office box or address other than the usual business address.

The customer requests unusual methods or routes of shipment or who provides unusual shipping, labeling or packaging instructions.

The customer prefers to pay by cashier's check, postal money order, etc.

The customer proposes using a freight forwarder as ultimate consignee.

The customer, whose communication either by telephone, mail, or other means, is not conducted or prepared in a professional business manner.

The customer purchases unusual quantities or combinations of chemicals or glassware in contrast with customary practice and usage.

The customer's stated use of listed chemicals is incompatible with destination country's commercial activities or consignee's line of business.

The customer's use of intermediate consignee(s) whose location or business is incompatible with the purported end user's nature of business or location.

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control
Suspicious Orders Task Force

Appendix C

The Comprehensive Methamphetamine Control Act of 1996 (MCA)